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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/600,118

06/20/2003

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EXAMINER

BOUCHELLE, LAURA A

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/600,118	Applicant(s) CIMINO, WILLIAM W.	
	Examiner LAURA A. BOUCHELLE	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/1/09 has been entered.

Claim Objections

2. Claims 11-15 are objected to because of the following informalities: Claims 11-15 recite "the method of claim 9..." The independent method claim is claim 10. For the purposes of this examination it will be assumed that claims 11-15 depend from claim 10. Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-9, 10-11, 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeSatnick et al (US 4650462) in view of Wheeldon et al (US 4670007). DeSatnick teaches a system for delivering a volume of sterile fluid to a targeted anatomical site, the system comprising a container of sterile fluid 16, a peristaltic pump 12 for pumping any amount of sterile fluid from the container to a targeted anatomical site, the pump having speed control 14 adjustable by the user (col. 3, lines 52-55), a sterile tubing set 20 for delivery of the fluid to the

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patient, and a display 40 for displaying the fluid delivery rate. The device is capable of handling flow rates of 0-999ml/min (col. 5, lines 39). The irrigation system is capable of being used in any procedure requiring sterile fluid delivery in the disclosed flow rate ranges.

5. DeSatnick inherently teaches the method of using the device including the steps of connecting the sterile tubing to the container, passing the tubing through a pump and making the other end available for delivery. The step of releasing the pump activation is inherently done at the end of the procedure.

6. Claim 1 differs from DeSatnick in calling for a strain gauge sensor and a processor for determining the volume of fluid delivered to the patient. Wheeldon teaches a device for controlling the amount of fluid delivered to a patient including a sterile fluid source attached to a strain gauge which monitors the delivery rate and displays either the delivery rate or the total dose amount on a display. Wheeldon teaches that monitoring the flow rate and volume delivered using a strain gauge is preferable to other methods known in the art such as monitoring the speed of a peristaltic pump as is disclosed by DeSatnick because it does not require calibration of the device and eliminates variations in tubing performance (col. 1, line 59 - col. 2, lines 40).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of DeSatnick to include the volume monitoring system of Wheeldon (including a strain gauge and processor) because Wheeldon teaches that using a strain gauge is preferable to simply monitoring the RPM of the pump because it allows for better control and accuracy and eliminates variables such as tubing performance.

7. Claim 10 differs from DeSatnick in calling for the steps of supporting the container from a strain gauge sensor and processing the signal from the sensor to display volume of sterile fluid

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delivered. Wheeldon teaches these steps. It would have been obvious to include these steps in the method for the reason discussed above with reference to the system.

8. Regarding claim 4, Wheeldon teaches that the display will "zero" when the device is turned off and then back on (col. 6, lines 50-54). Therefore the power button is interpreted to be the reset button. It would have been obvious to one of ordinary skill in the art at the time of invention to include this feature in the device of DeSatnick so that the display will automatically start at zero with every new use of the device.

9. Regarding claims 5, 8, 14, DeSatnick is silent as to the material of the tubing set. However, it is well known in the art to use polyvinyl chloride tubing sets for their durability, sterilibility, biocompatibility, and nonreactiveness. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the tubing set of DeSatnick to be formed of PVC as is well known in the art.

10. Claims 12, 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeSatnick in view of Wheeldon as applied to claim 10 above, and further in view of Maddock et al (U 5549672). Claim 12 differs from the teachings above in calling for the procedure to be the filling of breast implants. Maddock teaches a method of filling breast implants wherein the flow rate and pressure of the infusion fluid is precisely monitored and controlled using a pumping system that has volume measuring capabilities and pressure measuring capabilities, a bag and tubing set which allows for fast and accurate filling of the breast implants. See Abstract. It would have been obvious to one of ordinary skill in the art at the time of invention to use the device of DeSatnick in view of Wheeldon to fill breast implants because the device has all the requirements of that procedure as taught by Maddock.

Response to Arguments

11. Applicant's arguments filed 4/1/09, with respect to the rejection(s) of claim(s) 1-18 under Wheeldon in view of Hadzic have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of DeSatnick in view of Wheeldon.

12. The examiner acknowledges applicant's argument that Wheeldon teaches that the processor controls and adjusts the flow rate of the pump. DeSatnick meets the claim limitation of the processor not being electronically connected to the pump because the pump is manually controlled. The combination is essentially adding the strain gauge, processor and display of Wheeldon to the device of DeSatnick to overcome the shortcomings of relying only of the RPM reading which were discussed by Wheeldon. The examiner does not believe that making this combination requires the addition of the control feature of Wheeldon to the device of DeSatnick because Wheeldon is only being relied upon to teach that using a strain gauge and processor is a more accurate and precise way of monitoring the flow rate and volume than just relying on a calibration of the RPM reading.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Laura A Bouchelle
Examiner
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